

c

UNITED STATES DISTRICT COURT  
FOR THE DISTRICT OF DELAWARE

THE JOHNS HOPKINS UNIVERSITY, a	:	Case No. 94-105 RRM
Maryland corporation, BAXTER	:	
HEALTHCARE CORPORATION, a Delaware:	:	
corporation, and BECTON DICKINSON	:	
AND COMPANY, a New Jersey corporation,	:	
	:	
Plaintiffs,	:	
	:	
	:	
v.	:	
	:	
CELLPRO, INC., a Delaware corporation,	:	
	:	
Defendant.	:	
	:	

**DECLARATION OF DR. EDWARD BALL**

DECLARATION OF DR. EDWARD BALL

I, Edward Ball, M.D., do hereby declare:

1. I am a professor of medicine at the University of Pittsburgh Medical Center. A copy of my curriculum vitae is attached.
2. I am acquainted with the capabilities of CellPro's CEPRATE® SC stem cell concentrator. Indeed, the Medical Center was one of the five centers involved in the breast cancer treatment studies that led to the approval of the CEPRATE® SC device by the U.S. FDA.
3. I currently use the CEPRATE® SC device in two on-going investigational protocols. The first protocol involves a treatment for Gaucher disease. Gaucher disease is a metabolic disease that, left untreated, results in the failure of a patient's bone marrow. Experimental treatment for this disease involves transferring the missing gene into CD34+ cells selected by the CEPRATE® SC device. Our studies show that, when the cells are re-infused into the patient, the previously missing gene is expressed. The second on-going investigational protocol involves a two-step procedure for treatment of acute myeloid leukemia (AML). The AML treatment protocol involves selecting CD34+ cells using the CEPRATE® SC device, and then using the CEPRATE® SC device to purge tumor cells bound by an anti-myeloid monoclonal antibody that I developed.
4. In the future, I plan on using the CEPRATE® SC device in other protocols requiring peripheral blood or bone marrow CD34+ selection.

5. I have personally evaluated the Baxter ISOLEX CD34+ selection device, and found that it was not acceptable for my needs.

6. If the CEPRATE® SC device were not available, it would have a significantly negative effect on my ability to carry out the current and planned investigational protocols that I have described. Indeed, with regard to the Gaucher disease study, there would be no other options and the study would have to stop.

7. With regard to FDA approved, non-experimental protocols using the CEPRATE® SC device, that device provides reduced toxicity compared to conventional procedures. In the conventional procedure, a "buffy coat" containing hematopoietic stem cells is prepared and preserved using DMSO. However, both DMSO and other undesired cells in the buffy coat exhibit infusion toxicity.

8. I have also used CellPro's CEPRATE® LC laboratory column in the initial stages of developing the investigational protocols described above. If the CEPRATE® LC laboratory column had not been available, it would not have been possible to pursue these investigational treatment options.

9. There is a compelling public interest in maintaining the availability of both the CEPRATE® SC and CEPRATE® LC devices, not only for the investigational work that I have described above, but also for protocols being developed by others for gene therapy and cancer treatment.

I further declare subject to the penalty of perjury that the foregoing is true and correct.

Executed March 24, 1997 at Pittsburgh, Pennsylvania.

  
\_\_\_\_\_  
Edward Ball, M.D.

## BIOGRAPHICAL

NAME:	Edward D. Ball, M.D.	BIRTH DATE:	March 15, 1950
HOME ADDRESS:	9977 Parkland Drive Wexford, PA 15090	BIRTH PLACE:	Syracuse, NY
HOME PHONE	(412) 934-1242	CITIZENSHIP:	USA
BUSINESS ADDRESS:	Montefiore University Hospital 200 Lothrop Street Pittsburgh, PA 15213	SOCIAL SECURITY NO.:	191-40-6647
BUSINESS PHONE:	(412) 648-6413	SPOUSE NAME:	Susan E. B. Ball

---

EDUCATION AND TRAINING
UNDERGRADUATE:

1968 - 1972	University of Maryland College Park, Maryland	B.S., 1972	Biochemistry with high honors
-------------	--	------------	----------------------------------

GRADUATE:

1972 - 1976	Case Western Reserve University Cleveland, Ohio	M.D., 1976	Medicine
-------------	--	------------	----------

POST-GRADUATE:

1976-1979	Hartford Hospital	Resident, Internal Medicine	Ralph Reinfrank, MD
1979-1981	University Hospitals of Cleveland	Fellow - Hematology & Oncology	Oscar Ratnoff, MD
1982-1983	Dartmouth-Hitchcock Medical Center	Fellow - Hematology & Oncology	Gibbons G. Cornwell, III, MD

---

APPOINTMENTS AND POSITIONS
ACADEMIC:

1993-Present	Pittsburgh Cancer Institute Pittsburgh, PA	Director, Bone Marrow Transplant Program
1991-1993	Pittsburgh Cancer Institute Pittsburgh, PA	Co-Director, Bone Marrow Transplant Program
1991-Present	Pittsburgh Cancer Institute Pittsburgh, PA	Co-Director, Leukemia/Lymphoma Program
1991-Present	University of Pittsburgh Medical Center Pittsburgh, PA	Professor of Medicine Chief, Division of Hematology/Bone Marrow Transplantation
1987-1991	Dartmouth Medical School Hanover, NH	Associate Professor of Medicine and Microbiology
1987-1991	Dartmouth Medical School Hanover, NH	Adjunct Associate Professor of Biochemistry
1986-1987	Dartmouth Medical School Hanover, NH	Adjunct Assistant Professor of Biochemistry
1983-1987	Dartmouth Medical School Hanover, NH	Assistant Professor of Medicine and Microbiology
1982-1983	Dartmouth Medical School Hanover, NH	Assistant Professor of Microbiology